

**Department of Defense  
Health Care Provider's  
Briefing**

# **SMALLPOX**

**Version: 27 Dec 02**

# Purpose

- Purpose of this briefing is to prepare health-care providers to understand **smallpox & smallpox vaccination**
- Refer to **DoD Smallpox Response Plan** ([www.vaccines.army.mil/smallpox.asp](http://www.vaccines.army.mil/smallpox.asp)) for information about:
  - Surveillance for fever-rash illness
  - Epidemiologic response (contact tracing)
  - Other smallpox and vaccination issues

# Key Messages

- **Smallpox would disrupt military missions, because it is contagious and deadly**
- **Smallpox vaccine prevents smallpox, but requires very careful use**
- **Preserving the health and safety of our people are our top concerns**
- **Smallpox protection helps our War on Terrorism: New threats require new measures of force protection**

# Smallpox Threat

- Smallpox eradicated from the world in 1980
- Entire world's population is **susceptible**
- Significant **person to person** transmission
- Easily manufactured and disseminated
- **Low inoculum** needed
- Infamous for morbidity & mortality
- Significant **fear factor** & panic
- Overwhelm medical facilities
- No specific chemotherapy
- **Limited vaccine** supply
- Physicians are unfamiliar with the disease

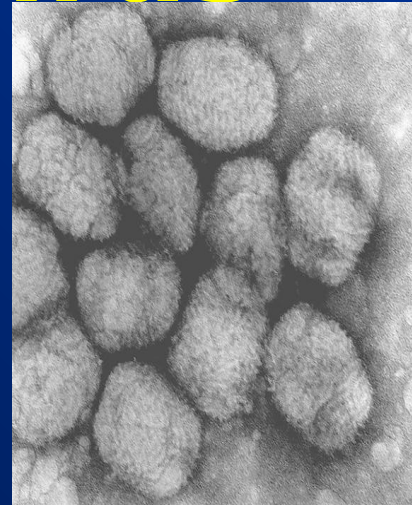
**= Perfect  
BioAgent**

# General Public's Knowledge

- 89% knew smallpox was contagious
- 30% & 63% thought smallpox occurred in last 5yrs in US or world, respectively
- 78% believe medical treatment is available to prevent death or serious dz after sx dev't
- 25% stated that they would likely die from the vax
- 41% were likely to have serious illness from vax
- only 27% thought that contact with recently vaccinated person could result in serious infection
- only 7% reported a contraindication for vax'n
- \*\*\* majority (79%) would decline vax'n if docs declined

# Smallpox (Variola) Virus

- **Orthopox (dsDNA) virus**
  - vaccinia, variola, cowpox, monkey pox
- **Only human reservoir**
- **Infectious Dose**
  - unknown, presumably only a few virions
- **Survivability (24 hrs to years)**
  - Inactivated by UV light, heat, bleach, alcohol, Lysol®
- **Transmission**
  - aerosol, respiratory, contact, fomites
  - “close” contacts = <2meters, 1-3hrs
  - 58% household contacts, avg 3-5/case



# Smallpox Epidemiology

- **Less contagious than measles, varicella, pertussis and influenza**
  - **Interval of 2-3 wks between cases**
  - **Secondary cases generally limited to household & hospital contacts**
  - **Interruption of transmission**
    - isolation of smallpox patients
    - locate/vaccinate contacts (1° and 2°)
    - isolate contacts who become ill
- “surveillance & containment”   “ring vaccination”**

# Smallpox Vaccination



NY Epidemic 1947



# Smallpox Vaccine in History

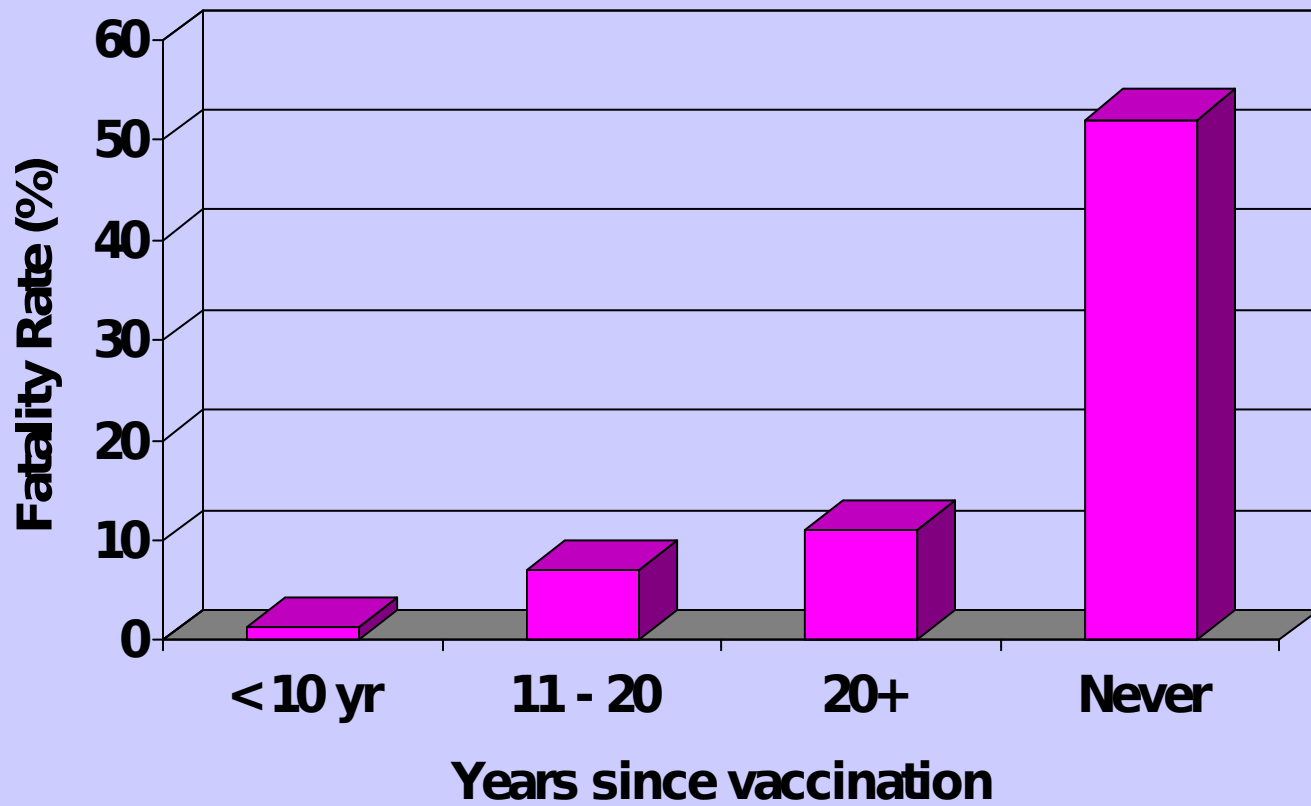
- **1776:** G. Washington orders variolation of Continental Army
- **1796:** Edward Jenner uses cowpox virus as “vaccination”
- **1812:** War Dept orders Jennerian vaccine of US troops
- **1931:** Dryvax® licenced by FDA
- **1949:** Last case of smallpox in US (TX)
- **1967:** WHO initiates aggressive campaign against smallpox
- **1971:** Discontinuation of routine vax'n in US
- **1976:** Discontinuation of vax'n of healthcare workers in US
- **1977:** Last case of natural smallpox (Somalia)
- **1980:** WHO declares Earth free of smallpox
- **1984:** DoD restricts vaccination to recruits at basic training
- **2002:** ~ **65% of AD personnel never vaccinated** for smallpox; almost whole force is susceptible to infection

# Smallpox Vaccine

- **General:** *Dryvax® (Wyeth Laboratories)*
  - **Content:** lyophilized live Vaccinia virus  
100 dose vial, FDA-approved (1:5 IND protocol)
  - **Diluent:** 50% glycerin, polymyxin B, streptomycin, tetracycline, neomycin, phenol (as preservative)
  - **Delivery:** Intradermal inoculation with bifurcated needle (scarification method)
  - **Result:** pustular lesion or area of induration surrounding a central lesion (scab or ulcer) 6-8 days after vaccination
  - **Efficacy:** 95% primary vaccinees (within 10d)
  - **Post-exposure:** within 3-4 days, no or mild disease.

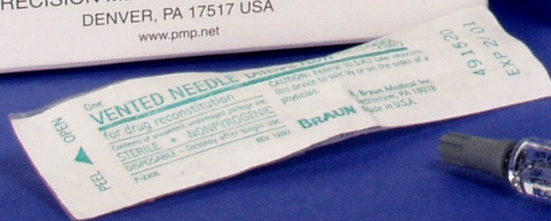
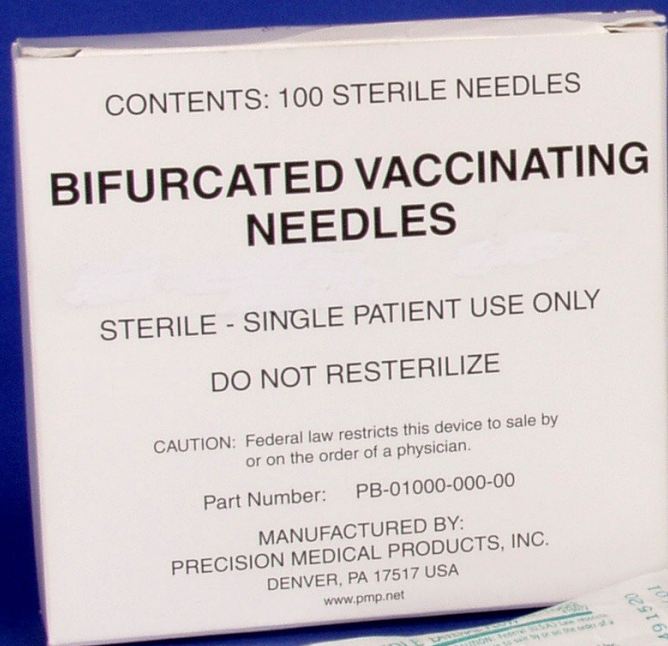
# Duration of Protection

Smallpox Fatality Rate by Time Since Vaccination  
Europe, 1950 - 1971\*



\*Mack, TM. J Infect Dis 1972; 125:161-9







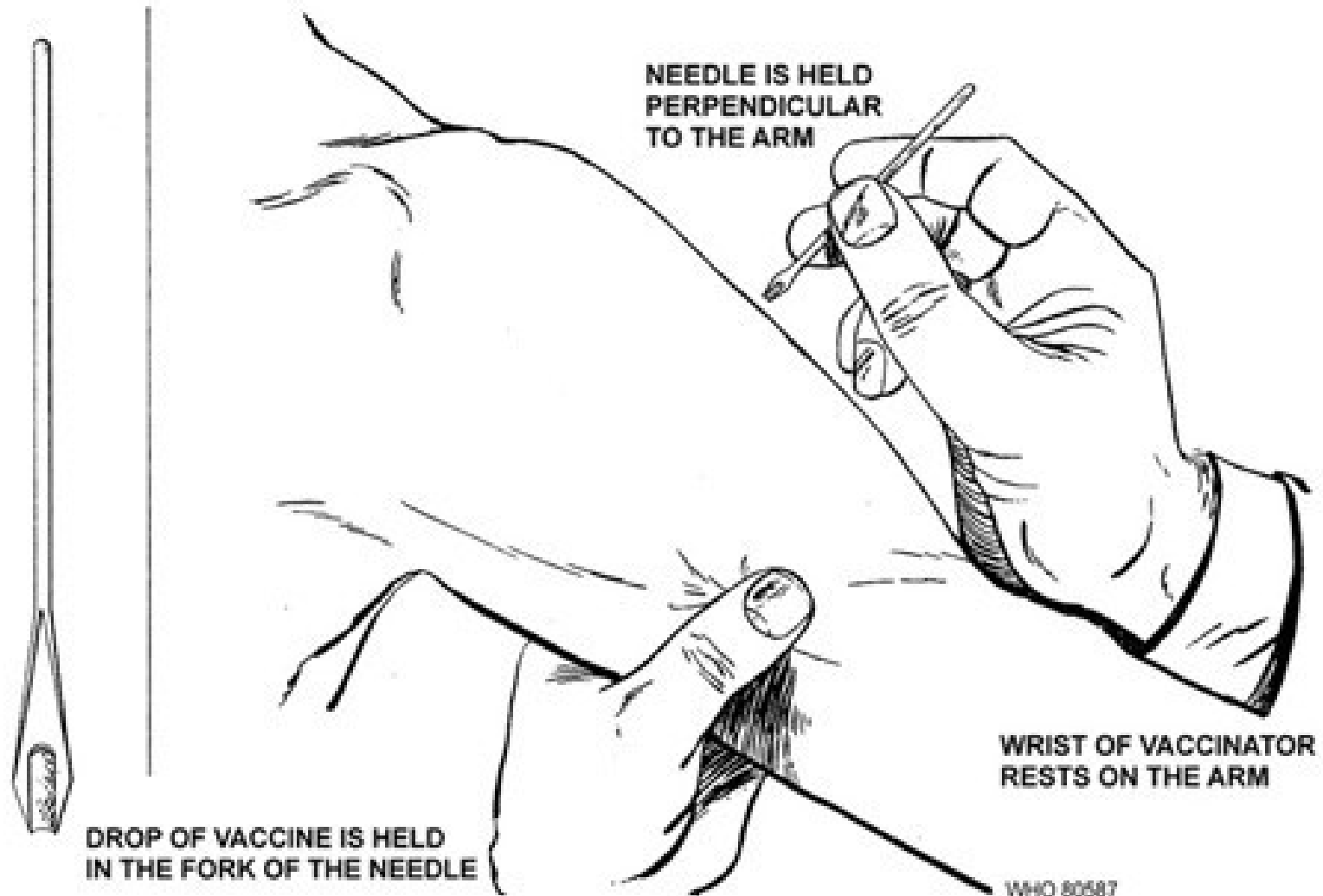
# Vaccination Technique

- **Site:** Skin over deltoid or posterior arm over triceps
- **Cleanse site** (soap & water, acetone or alcohol)
- **Multiple-puncture technique:** uses bifurcated needle inserted vertically into the vaccine vial
- **Primary (first) vaccination:** 3 punctures, rapidly in 5 mm area, with strokes vigorous enough to cause a trace of blood after 15-20 seconds
- **Revaccination:** 15 punctures
- **Evidence of prior smallpox vaccination:** (descending order of reliability)
  - medical documentation
  - characteristic Jennerian scar
  - entry into U.S. military service before 198
  - birth in the United States before 1970

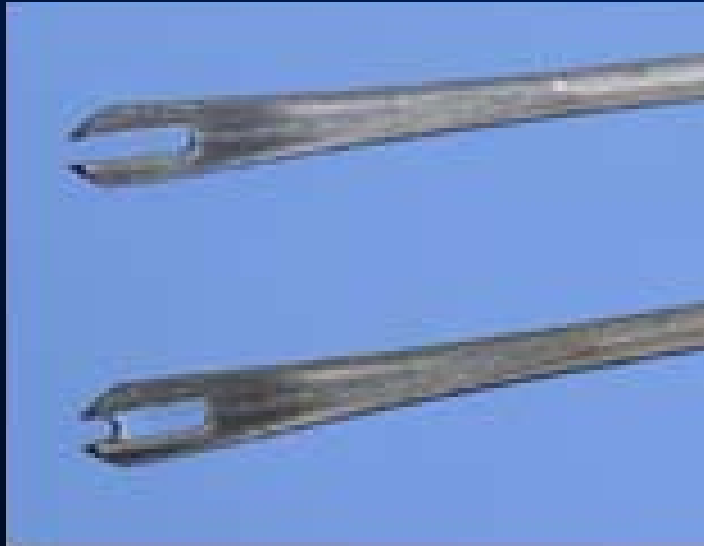


# Vaccination Technique

## MULTIPUNCTURE VACCINATION BY BIFURCATED NEEDLE



# Vaccination Technique

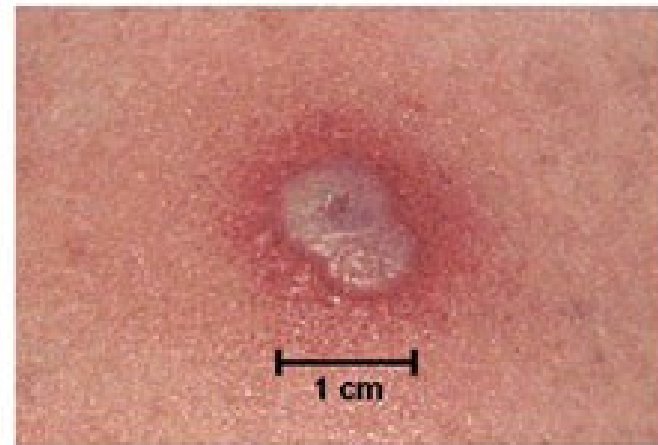


# Typical Reaction

## Primary Vaccination Site Reaction



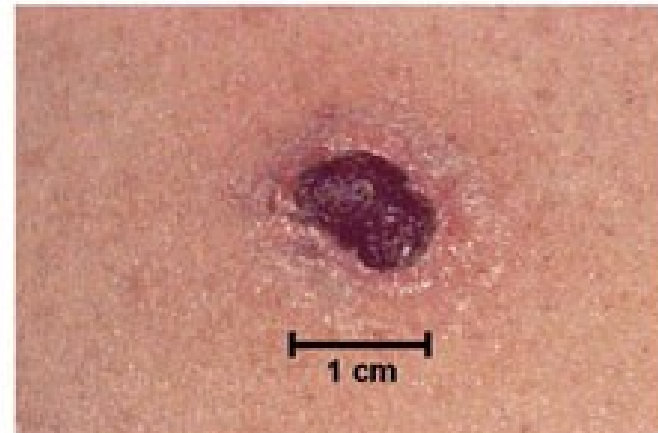
**Day 4**



**Day 7**



**Day 14**



**Day 21**



# Smallpox Vaccination

## Vaccination assessed 6-8 days later:

- Major (primary) reaction
  - successful vaccination s/p viral replication
  - vaccinee considered protected
- Equivocal reaction
  - lack of an appropriate immune response
  - indicates:
    - impotent vaccine
    - poor vaccination technique
    - previously immune
    - allergic reaction w/o immune response
    - immune suppression

# Revaccination

## Revaccination, if no take:

### **If no reaction:**

- Repeat vaccination with 15 punctures (jabs)
- Do not revaccinate more than once in short term

### **If still no (suboptimal) reaction after 2nd attempt:**

- If primary vaccination: Refer for immunologic evaluation.
- If previously vaccinated: Consider medically immune

## Revaccination, booster interval:

- Booster if > 3-5 yr elapsed after first vaccination
- Booster if > 10 yr elapsed after later vaccination

# Documentation

- **Screening:** Recorded on SF600;  
Contraindications recorded on SF600 & DD2766
- **Vaccination:** SF600, SF601, DD2766 and SAMS
- **Confirmation of successful vaccination:**
  - Instruct all: Come back to clinic for documentation, **ESPECIALLY** if no characteristic lesions develop
  - Recorded in medical record as above
  - May be recorded on PHS-731 (yellow card)  
International Certification of Vaccination
- **Adverse events:**
  - Medical records, VAERS, VHC access
- **USD(P&R):** Services will audit immunization tracking systems

# Smallpox Vaccine Contraindications

Some people should not get smallpox vaccine, except under emergency situations. A Medical Exemption is given IF:

- **Allergies to vaccine components**
  - streptomycin, tetracycline, polymyxin B, neomycin
- **Pregnant or Breastfeeding**
- **Immunosuppression or Immunodeficiency**
  - HIV, cancer, transplant, autoimmune d/o, steroids, meds, chemotherapy, XRT
- **History or current eczema / atopic dermatitis**
  - scaly, red itchy rash, lasts ~2wks, intermittent
- **Household/close contacts with above**

# Smallpox Vaccine Precautions

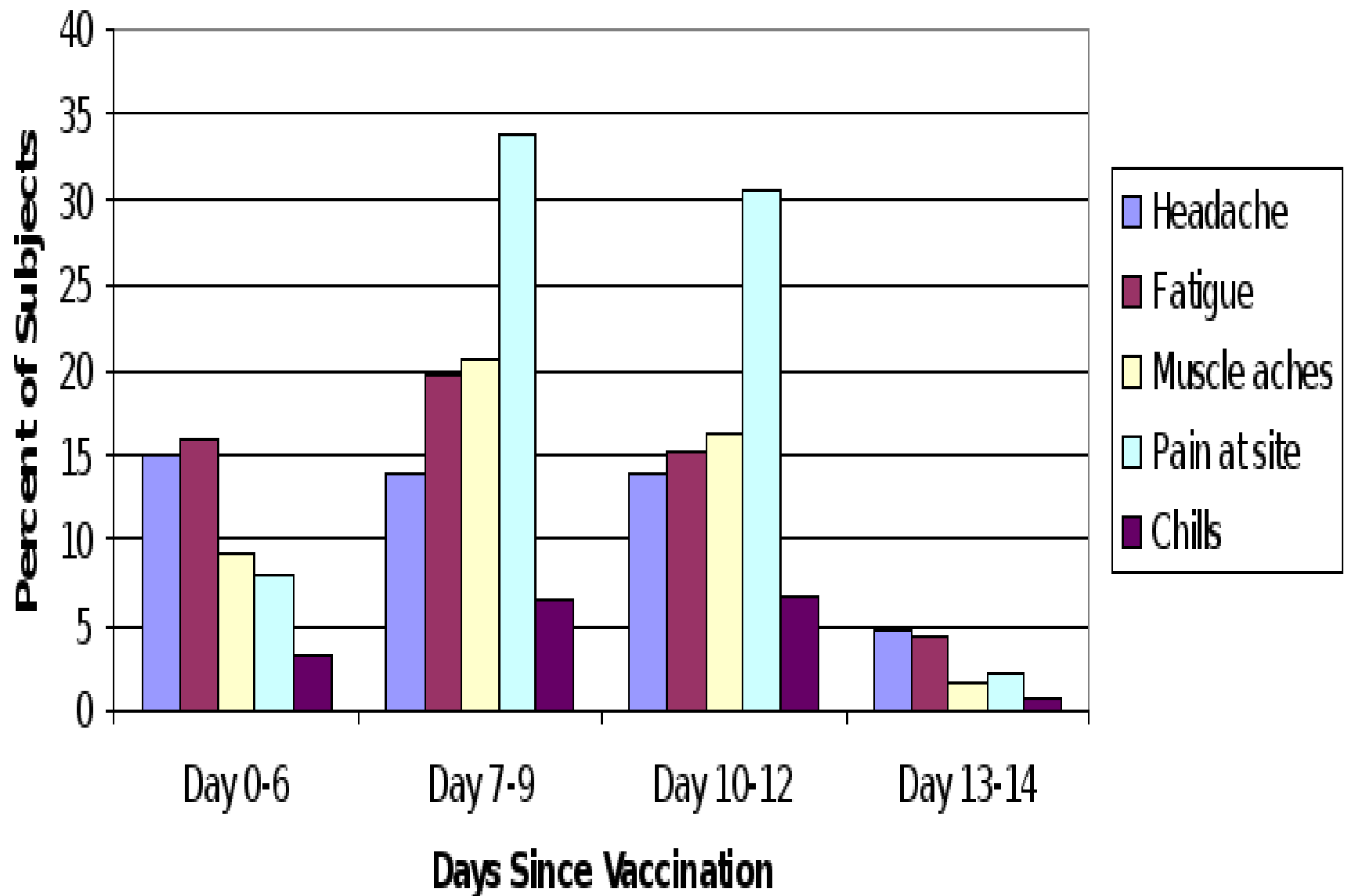
- **Households with Infants** (< 1yr old)
  - relative contraindication
  - want to minimize transmission
- **Active derm lesions**
  - psoriasis, burns, impetigo, uncontrolled atopic dermatitis, chickenpox, contact dermatitis
  - relative... may give vax once lesions controlled
- **Women should not become pregnant** (x4wks)
- **Passive Immunity (VIG)**
  - only for severely immunocompromised, or contacts w/ Vax contraindications



# Vaccine Safety

- Carefully read & complete screening form
  - You are helping accurately document that it is safe to give you the vaccine
- Ask questions if you are unsure
- Contact family members who may know about childhood history of recurrent rashes like eczema
- Talk to close contacts and family members about the vaccination program and safety precautions
- Ask for assistance at any point, if needed by you or your close contacts or if you have safety concerns

# Side Effect Profile



# Adverse Events

- Otherwise rare, if adequate screening and appropriate precautions
  - In past, about 1,000 out of 1,000,000 (0.1%) people had reactions that were serious, but not life-threatening
  - Most involved vaccine virus elsewhere on body (autoinoculation)
  - Many preventable through better hand washing!
  - Can significantly reduce risk of side effects, by exempting people with immune problems or certain skin conditions
- 14 - 52 people per 1,000,000 (.005%) primary vaccinees had potentially life-threatening reactions
  - 1 - 2 people of 1,000,000 primary vaccinees may die (PVE/PV)
  - 1 for every 4,000,000 secondary vaccinee may die
- Serious side effects are less common w/ revaccination
  - Occurs 10x more often in primary vax'n
  - More frequent in infants, than kids/adults (now only vax >18yo)



# Adverse Reactions

- See 16-panel CDC color brochure:
  - *Smallpox Vaccination: Methods & Reactions*
- See also additional images at [www.bt.cdc.gov/training/smallpoxvaccine/reactions](http://www.bt.cdc.gov/training/smallpoxvaccine/reactions)



# A/E - Autoinoculation



- **Most commonly on face, eyelid, nose, mouth, rectum, & genitalia**
- **Most lesions heal w/o specific therapy, but some scarring.**
- **Rate = 1/1890 (529)**

# A/E - Generalized Vaccinia



- Generalized viremia resulting in pustules, self-limited, generally no therapy, rarely “toxic”
- Other rashes can occur (incl. E. multiforme), but generally afebrile
- Rate = 1/4,000 (242)

# A/E - Progressive Vaccinia



- *aka vaccinia necrosum*
- Progressive necrosis associated with cellular (+/- humoral) immune deficiency.
- Once widely fatal, can treat with VIG, cidofovir
- Rate = 1/600,000 (1.5)

# A/E - Eczema Vaccinatum



- Localized or systemic dissemination of vaccinia, with either active or quiescent dz in patients with eczema, atopic dermatitis, other exfoliative dz
- 1/3 occurs in contacts
- May be severe or fatal
- Rate = 1/25,000 (39)

# **A/E - Post Vaccinial Encephalitis**

- **Primarily affects primary vaccinees**
- **Highest risk among children <1 yr**
- **Believed to result from autoimmune or allergic reaction**
- **Frequently fatal or permanent sequelae**
  - **~25% die, ~25% sequelae**
- **Rate = 1/83,000 (12)**

# Serious Adverse Events

- Serious reactions that may require medical attention:
  - Accidental spread of virus to another body part or person
  - Widespread rash where sores break out away from vaccination site (generalized vaccinia)
  - Allergic rash after vaccination (erythema multiforme)
- Life-threatening reactions that need immediate attention:
  - Serious skin rashes in people such as those with eczema or atopic dermatitis (eczema vaccinatum)
  - Ongoing infection of skin with tissue destruction (progressive vaccinia or vaccinia necrosum)
  - Postvaccinal encephalitis, inflammation of the brain



# Treatment of Adverse Events

- Be alert for serious, rare, adverse events after vaccination (e.g. pericarditis, osteomyelitis, etc.)
  - most of our previous primary data is from young kids
- Consult as appropriate with critical care, dermatology, neurology, allergy/immunology, infectious disease, or other subspecialist(s).
- Some conditions respond to vaccinia immune globulin (VIG) and/or Cidofovir
  - VIG consists of human IgG antibody from people vaccinated with smallpox vaccine
  - VIG and Cidofovir available only under IND protocol (USAMRIID vs. TAMC)



# VIG & Cidofovir

|                             | VIG | Cidofovir |
|-----------------------------|-----|-----------|
| Post Vaccinial Encephalitis | X   | X         |
| Eczema Vaccinatum           | Yes | Yes       |
| Progressive Vaccinia        | Yes | Yes       |
| Generalized Vaccinia        | Yes | Yes       |
| Ocular Auto-inoculation     | Yes | Yes       |
| Vaccinial Keratitis         | X   | X         |
| Smallpox                    | X   | Yes       |

# Adverse Event Reporting

- **Vaccine Adverse Event Reporting System (VAERS)**
  - FDA and CDC review 100% of adverse-event reports submitted to VAERS
  - Anyone can submit a VAERS form
  - Reporting with medical help is preferred
- **DoD requires a VAERS form submission for:**
  - Loss of duty 24 hours or longer ( $\geq$  1 duty day)
  - Hospitalization
  - Suspected vaccine vial contamination
- **Other submissions encouraged**

Report to VAERS at [www.vaers.org](http://www.vaers.org) or call 800-822-7967

# Specific Topics



# Co-Administration with Other Vaccines

- ACIP accepts administration of live and inactivated vaccines simultaneously or at any interval
- The only major restriction to combining vaccinations is with multiple live-virus vaccines
  - Either give simultaneously or separate by 28+ days
- Separate varicella (chickenpox) and smallpox (vaccinia) vaccinations by 28 days, to avoid confusing lesions
- Do not administer other vaccines near

# Blood Donation

- **Because of viremia and other concerns regarding vaccinia transmission:**
  - **Defer for 21 days or when the scab spontaneously falls off whichever longer**
  - OR**
  - **Defer for 2 months if scab is removed**

# HIV Infection

- HIV infection is a bar to smallpox vaccination
- Service Members will be up-to-date with HIV-screening before smallpox vaccination
- DoD civilian employees and contractors will be offered HIV testing in confidential setting, with results before vaccination
- HIV testing recommended for anyone with history of risk factor for HIV infection, especially since last HIV test, and not sure of HIV-infection status
- Because known risk factors cannot be identified for some people infected with HIV, people concerned they could be infected should be tested

# Pregnancy & Infant Care

- **Defer routine smallpox vaccinations while pregnant:**
  - When pregnant women get smallpox vaccine, pregnancy usually goes well
  - In rare cases, vaccine caused fetal vaccinia (50 cases)
- **Avoid getting pregnant 4wks after vaccination**
- In an outbreak, personal benefit from vaccination may outweigh risks
- **Smallpox vaccine not recommended for nursing mother**, as it could put infant in close contact with mother's vaccination site
- **Take care to prevent spread of vaccine virus to infants** < 1 yr of age. Wash hands before handling infant (e.g., feeding, changing diapers)



# Alternate Housing

- People who have household contact with person with bar to smallpox vaccination shall:
  - either have alternative housing arrangements
  - or be exempted from smallpox vaccination until household-contact situation no longer applies (i.e., scab falls off)

**Unacceptable:** Permitting vaccinated SM to reside in house, trailer, apartment, or similar close arrangements (e.g., “hot-bunking”) with medically-barred contact

**Acceptable:**

- Vaccinated SM uses alternate lodging (e.g., barracks, dorm room, tents) on military installation, vessel, or aircraft, or in contracted space
- Berthing barges, familiar to naval forces in shipyards
- Vaccinated SM voluntarily arranges for alternate lodging in privately-owned or managed space is acceptable, if commander has reasonable expectation that SM will comply with requirement
- Schedule vaccinations shortly before or during 21-day deployments or family separation

# Care of Vaccination Site



# Care of Vaccination Site

**Vaccine virus remains at the site, until scab falls off & can infect others**

- Vaccine recipients need to be careful and informed
- Vaccine recipients need to educate close contacts about risk
- **Don't touch any vaccination site**
- **If you touch it by accident, wash your hands right away**
- **Don't let others touch vaccination site or materials that covered it**
- Wear gloves if assisting with site care
- **Handle your own laundry/towels and place in hot soapy water directly**



*This woman touched her vaccination site, then touched her eye. She recovered with a scarred eyelid.*

# Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if anything is unclear.

- Avoid spreading vaccine virus to close contacts until your scab falls off, particularly with people exempted from getting vaccinated
- Do not share a bed, bunk, or cot with people who are exempted from vaccination
  - Anyone is at risk for vaccine virus contact infection, so **Wash Your Hands!**
- Do not share clothes, towels, linen, or toiletries
  - Anyone is at risk for vaccine virus contact infection, so **Wash Your Hands!**

# Care of Vaccination Site

Follow these instructions carefully, or you could harm yourself or others. Ask questions if anything is unclear.

- Wear long sleeves to cover the site.
- Use bandages, if needed. Dispose of bandages in sealed or double plastic bags. You may carefully add bleach, alcohol, or soap, if desired
- Keep site dry, except normal bathing. Avoid rubbing. Avoid swimming or public bathing facilities
- Launder clothing, towels, and sheets in hot water with detergent or bleach.
- When the scab falls off, flush it down the toilet. Soap, alcohol, sunlight, chlorine, and bleach kill the virus.
- Wash your hands – Hand washing hand washing!<sup>44</sup>

# Hand Washing & Hand Hygiene

- Wash hands with soap and warm water
  - rub hands together vigorously **for at least 10 seconds**
  - cover all surfaces of the hands and fingers
  - rinse hands with warm water
  - dry hands thoroughly with a **paper towel**
  - use paper towel to **turn off the faucet**
- **Alcohol-based waterless hand rinse** *e.g., Calstat®*
  - Excellent alternative if hands are not visibly soiled
  - Apply product to palm and rub hands together, covering all surfaces of hands and fingers, until hands are dry
  - May have sticky feel after repeated use – wash hands with soap and water as needed



# Hand Washing & Hand Hygiene

To prevent accidental virus exposure to the genital or rectal area, wash your hands **BEFORE** using the



After using the toilet, **Wash your hands again!**



**Be extremely careful with your contact lenses!**

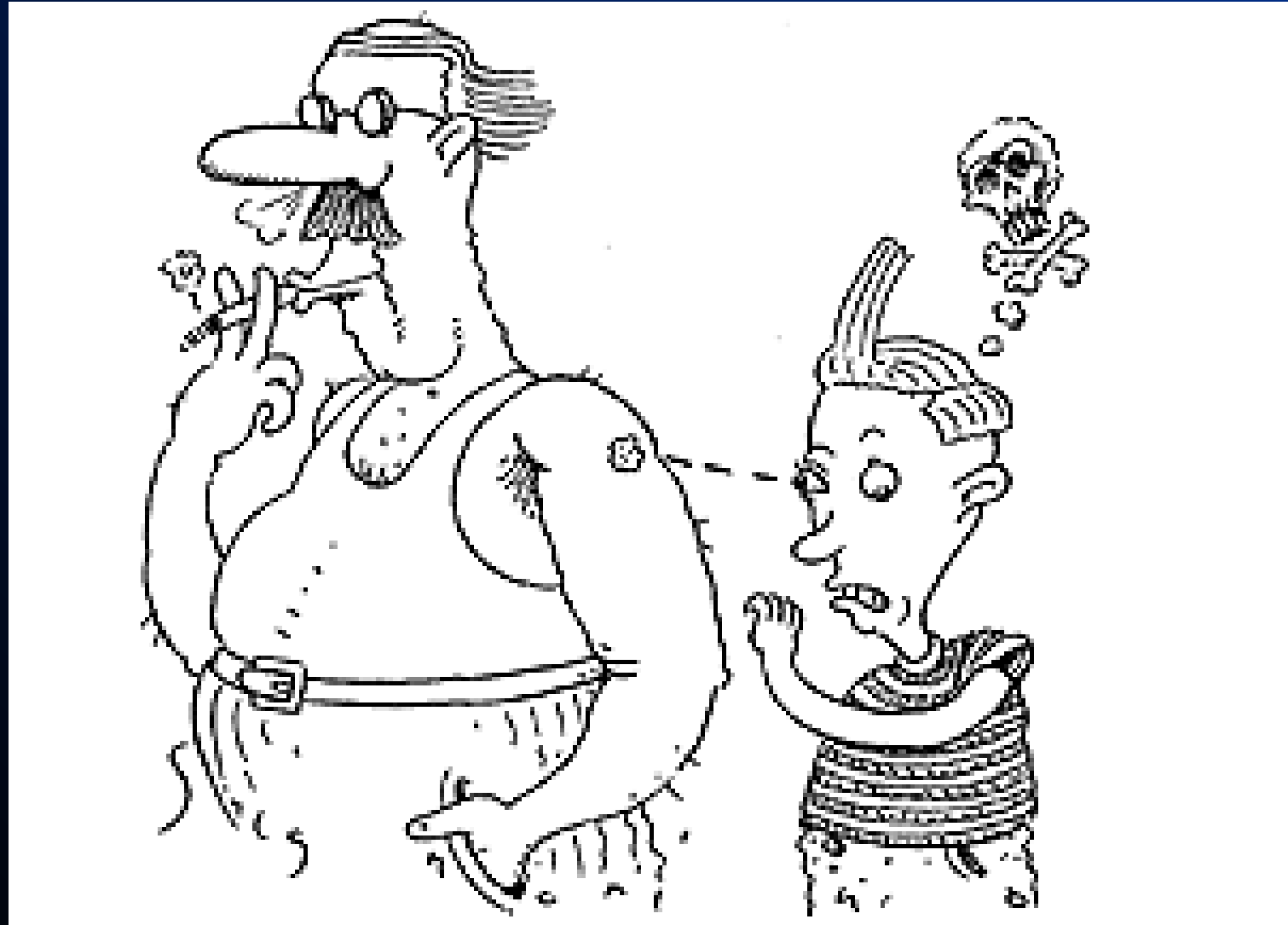
- Wash hands thoroughly before you touch your eye or the lenses
- Wearing your glasses until site heals is preferred



# Extra Cautions for Healthcare Workers

- Minimize contact with unvaccinated patients until scab falls off
- If contact essential and unavoidable, workers can continue to work with patients, including those with immunodeficiencies:
  - If site well-covered and thorough hand-hygiene maintained
  - Semi-permeable bandage (Opsite, Tegaderm, Cosmopore)
- To prevent accumulation of exudates, cover site with dry gauze, and then apply dressing over gauze
- Change dressing daily or every few days (according to type of bandaging and amount of exudate), eg, start or end of shift.
- Site-care stations: to monitor worker vaccination sites, promote effective bandaging, and encourage scrupulous hand hygiene
- Long-sleeve clothing can further reduce risk for contact transfer
- Most critical measure: Thorough hand-hygiene after changing bandage or any contact with site

# Be SMART!!!



# USNH Vax'n Plan



# USNH Smallpox Vax'n Plan

- As per Presidential directive, in accordance with DoD Smallpox Vaccination Program, based on DoD and CDC's Smallpox Response Plan and ACIP Vaccinia Recommendations...
- Will vaccinate **Stage 1A and 1B** for “pre-outbreak” preparations
  - Stage 1A - Smallpox (Epi) Response Teams
  - Stage 1B - “Selected” healthcare workers
  - Stage 2 - Other designated forces (Component UIC)

# **Selected Healthcare Providers**

- **ER Providers**
- **FP Providers**
- **PEDS Providers**
- **Consultants**
  - **ICU / Derm / Neuro**
  - **IM (x2)**
  - **G. Surg (x2)**
  - **Anesthesia (x2)**
  - **Ophtho (x2)**
  - **OB/Gyn (x2)**
  - **NICU (x2)**
- **ER Staff (incl EMTs)**
- **ICU Staff**
- **3E Staff**
- **BMC Staff**
- **PMT's**
- **Radiology Techs**
- **Respiratory Techs**
- **Laboratory Staff**
- **Security**

# Vaccination Process

## Part A - Screening of Personnel

- **Prescreen / Selection of candidates**
  - prescreened by DH or Div-O
  - nondeployable, h/o previous vax, on OKI >6mo, no personal (+/- family) contraindications
  - if family contraindications, we may elect to temporarily house AD members x3wks.
- **Individual Briefing, fill out SF600**
- **Medical Screening (1:1 interview)**
  - order lab tests, refer for consults, etc.
- **Provide Information (VIS)**

# Vaccination Process

## Part B - Vaccination of Personnel

- **Briefly re-screen staff members**
  - no acute illness, not pregnant, no active derm lesions, no new information
- **Vaccinate**
- **Give wound care instructions**
- **Document on SF600, SF601, DD2766**
- **Enter into SAMS**



# Vaccination Process

## Part C - Post Vaccination Care

- **Check site qDay before shift**
- **Dressing changes available BID**
  - AM (0615 - 0800)
  - PM (1800 - 1930)
- **Confirm take at days 6-8**
- **All care to be handled by Sick Call**
  - ensures conformity, adequate tracking
- **Complications to be reported to VAERS via EPI office**

# **Reserve (or TAD/LEAVE) Adverse-Event Care**

- **Adverse events after DoD- or USCG-directed vaccinations are line-of-duty conditions**
- **Someone with an adverse event in a non-duty status possibly associated to any vaccination:**
  - **Seek medical evaluation at a DoD, USCG, or civilian medical treatment facility, if necessary**
  - **Must report the event to your unit commander or designated representative as soon as possible**
  - **See local medical department or squadron for guidance**
- **Commander will determine Line of Duty and/or Notice of Eligibility status, if required**

# More Information



- **USNH Website**

- excellent resources (NEJM, ACIP, pix, etc.)
  - [www.oki.med.navy.mil](http://www.oki.med.navy.mil)

- **CDC Website**

- including CDC Smallpox Response Plan
  - [www.bt.cdc.gov](http://www.bt.cdc.gov)

- **Military Vaccine Website**

- including DoD Smallpox Response Plan
  - [www.vaccines.army.mil/smallpox](http://www.vaccines.army.mil/smallpox)

# ***Information Sources***

- Chain of Command
- Website: **[www.smallpox.army.mil](http://www.smallpox.army.mil)**
- E-Mail: **[vaccines@amedd.army.mil](mailto:vaccines@amedd.army.mil)**
- Toll-Free: **877.GET.VACC**
- CDC National Immunization Hotline: **800.232.2522**
- CDC Bioterrorism Information: **[www.bt.cdc.gov](http://www.bt.cdc.gov)**
- Walter Reed Vaccine Healthcare Center, for help with complicated adverse-event management: **202.782.0411**
  - **[Askvhc@amedd.army.mil](mailto:Askvhc@amedd.army.mil)**     **[www.vhcinfo.org](http://www.vhcinfo.org)**
- Information for Civilian Healthcare Providers: The Military Treatment Facility (MTF) where the member is enrolled, OR contact The Military Medical Support Office (MMSO) **888-647-6676** if the member is not enrolled to an MTF.

# *Questions?*

